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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES ex rel. LOUIS F. GILLIGAN; GREGORY M. UTTER,

Plaintiffs/Relators-Appellees,

v.

MEDTRONIC, INC.,

Defendant-Appellant.

No. 03-4213

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 98-00248—S. Arthur Spiegel, District Judge.

Argued: November 4, 2004

Decided and Filed: April 6, 2005

Before: COLE and ROGERS, Circuit Judges; COHN, District Judge.*

COUNSEL

ARGUED: Patrick F. McCartan, JONES DAY, Cleveland, Ohio, for Appellant. Gerald J. Rapien, TAFT, STETTINIUS & HOLLISTER, Cincinnati, Ohio, for Appellees. **ON BRIEF:** Patrick F. McCartan, Stephen G. Sozio, JONES DAY, Cleveland, Ohio, Jesse A. Witten, JONES DAY, Washington, D.C., Virginia C. Whitman, LAW OFFICE OF VIRGINIA CONLAN WHITMAN, Cincinnati, Ohio, Thomas M. Parker, PARKER, LEIBY, HANNA & RASNICK, LLC, Akron, Ohio, for Appellant. Gerald J. Rapien, TAFT, STETTINIUS & HOLLISTER, Cincinnati, Ohio, Jason M. Cohen, Joseph M. Callow, Jr., KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellees. Richard A. Samp, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amicus Curiae.

OPINION

R. GUY COLE, JR., Circuit Judge. Relators Louis F. Gilligan and Gregory M. Utter brought an action on behalf of the United States, under the False Claims Act, against Medtronic, Inc. ("Medtronic"), alleging Medicare fraud. Medtronic moved to dismiss the action on three grounds: (1) lack of subject matter jurisdiction under the False Claims Act; (2) failure to state a claim upon which relief could be granted; and

*The Honorable Avern Cohn, United States District Judge for the Eastern District of Michigan, sitting by designation.

(3) *res judicata*. The district court denied the motion as to all three claims. Medtronic thereupon filed a motion for leave to appeal the district court's denial of its motion to dismiss, which this Court granted. Medtronic now argues that the district court erred in denying the motion to dismiss. Because we find that the claims in this action were previously disclosed and trigger the public disclosure bar of the False Claims Act, we hold that the district court did not have subject matter jurisdiction and that dismissal was appropriate. Accordingly, we **REVERSE** the judgment of the district court and **REMAND** for proceedings consistent with this opinion.

I. BACKGROUND

Defendant-Appellant Medtronic is a medical-device manufacturer. Medtronic manufactures four types of heart pacemaker leads which are the subject of this litigation: Models 4004, 4004M, 4504, and 4504M. In 1988, Medtronic filed an application with the FDA for Premarket Approval of Models 4004 and 4504. The FDA approved the devices in a letter stating "[f]ailure to comply with the conditions of approval invalidates this approval order." The FDA attached the conditions of approval, which included a requirement that the company submit a supplemental Premarket Approval application "[b]efore making any change affecting the safety or effectiveness of the device." The conditions also required that the company submit annual reports that identify changes to the product, regardless of the changes' impact on safety or effectiveness, stating that "[c]ontinued approval of this PMA is contingent upon the submission of post-approval reports . . . ."

In 1989, Medtronic changed the coating of two of the leads to a platinum sputter coating. The company filed supplemental applications for Premarket Approval for the subject leads, Models 4004M and 4504M. After the FDA approved the applications, Medtronic altered the design specifications of the two leads, changing the thickness and coverage of the platinum sputter coating. Medtronic did not file a new Premarket Approval application or identify the change in the annual postapproval report filed with the FDA. However, the FDA's conditions of approval did not specify a required platinum sputter coating thickness or coverage. Furthermore, Medtronic did not submit information to the FDA in the premarket approval process that specified the new thickness or coverage of the platinum sputter coating.

Thereafter, a large number of the leads manufactured by Medtronic malfunctioned and had to be replaced. On the basis of this malfunction, relators Gilligan and Utter brought various products liability actions on behalf of individuals who used the malfunctioning leads. In these actions, the attorneys alleged, among other things, "fraud on the FDA" claims. The claims related to Medtronic's alleged misrepresentations to the FDA regarding the safety of the platinum-sputter-coated leads, fraud surrounding the manufacture of the leads, and deviation from design specifications.

Based upon the knowledge they gained through litigation of these product liability actions, Gilligan and Utter brought a *qui tam* action on behalf of the United States under the False Claims Act. They alleged that: Medtronic sold leads to physicians and hospitals, which then implanted the leads and billed Medicare for their services; Medtronic did not have FDA approval for the devices because it altered the coating after approval; and by selling the leads to doctors and hospitals, Medtronic caused the submission of false claims to Medicare. This submission was allegedly a fraud on the government and therefore, Gilligan and Utter theorized, it formed the basis for a *qui tam* action under the False Claims Act.

In the district court, Medtronic filed a motion to dismiss based on the aforementioned three grounds: (1) lack of subject matter jurisdiction; (2) failure to state a claim; and (3) *res judicata*. The district court denied the motion.

II. ANALYSIS

A trial court's denial of a motion to dismiss for lack of subject matter jurisdiction is reviewed *de novo*. *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 938 (6th Cir. 1997).

At the outset, we must determine whether the district court erred in denying Medtronic's motion to dismiss for lack of subject matter jurisdiction. The district court exercised subject matter jurisdiction over this suit under the False Claims Act. 31 U.S.C. § 3730(b). The False Claims Act bars jurisdiction where "allegations or transactions" have been publicly disclosed in, *inter alia*, a civil hearing or administrative report. 31 U.S.C. § 3730(e)(4)(A). Where information has been publicly disclosed, the government has access to enough information to bring a civil action and the citizen-suit provision becomes unnecessary. This jurisdiction-stripping rule does not apply where the party bringing the claim is the Attorney General or an "original source of the information." *Id.*

Relators in this case concede that they are not original sources. Therefore, this Court must determine whether the allegations or transactions at issue were publicly disclosed prior to the filing of the relators' complaint. To do so, the Court must determine first whether there has been any public disclosure of fraud, and second whether the allegations in the instant case are "based upon" the previously disclosed fraud. *United States v. Bledsoe*, 342 F.3d 634, 645 (6th Cir. 2003).

There are two parts to the theory that constitutes relators' *qui tam* suit. The first part is that the alteration of the platinum sputter coating rendered the leads manufactured by Medtronic unapproved by the FDA. The second part, which necessarily relies on the first claim, is that because the devices were rendered unapproved, the submission of Medicare claims by doctors constituted fraud. We will consider first whether there was any prior public disclosure of the allegations relating to the alterations in the platinum sputter coating. Then we will address whether the current case, including the allegation of Medicare fraud, is "based upon" the prior public disclosure, if any.

A. Public Disclosure

Generally speaking, we do not require specific disclosure of fraud to find public disclosure. So long as the information alleged is sufficient to put the government on notice of the likelihood of related fraudulent activity, the prior public disclosure requirement is satisfied. *Dingle v. Bioport Corp.*, 388 F.3d 209, 214-215 (6th Cir. 2004). There are two types of disclosures that this Court has found sufficient to put the government on notice of fraud. First, if information about both a false state of facts and the true state of facts has been disclosed, we should find that there has been adequate public disclosure because fraud is implied. *Id.* at 212 (holding that if information about both a false state of facts and the true state of facts is available to the government, an inference of fraud is reasonable and the justification for the citizen suit provision of the False Claims Act is no longer applicable). Second, if there has been a public allegation of fraud, the Court should also find public disclosure. *Id.* A public allegation of fraud, regardless of the specificity of the allegation, is also sufficient to put the government on notice of the potential existence of fraud, thus eliminating the justification for the citizen-suit provision of the False Claims Act.

1. Disclosure of False State of Facts and True State of Facts

Relators allege that the prior disclosures do not contain information about the platinum sputter alterations. Relators further allege that these alterations, made after FDA approval of the leads, rendered the products unapproved. Under relators' theory of the case, the true state of facts would be that Medtronic altered the thickness and coverage of the platinum sputter coating after FDA approval. The false state of facts would be that the product was the same product previously approved by the FDA.

The false state of facts was previously disclosed. Medtronic represented to the public that the leads were FDA-approved, and implicitly, that it had complied with FDA regulations and guidelines sufficient to maintain the FDA-approved status of the product.

The true state of facts was also previously disclosed. In several prior products liability cases, including *North v. Medtronic, Inc.*, No. 97-2-16954-2SEA (Wash. Super. Ct. July 7, 1997), the plaintiffs alleged that Medtronic (1) told the FDA that it had cured the problems with the leads by using a platinum sputter coating, (2) engaged in fraudulent conduct in the manufacture of the leads, and (3) deviated from

the design specifications. Relators argue that these allegations are insufficient to constitute prior disclosure of the allegations in the current *qui tam* action because the prior allegations did not specifically link Medtronic's alteration of the platinum sputter coating with the claims of fraudulent manufacture and deviation from design specifications. However, a specific link between pieces of information necessary to create an inference of fraud is not required.

This Court has previously held that public disclosures contained in different sources, which together provide information that leads to a conclusion of fraud, trigger the public disclosure bar. *See Dingle*, 388 F.3d at 213-14 (finding public disclosure where part of the relevant information came from a journal article and part came from a House of Representatives report). Here, the information necessary to create the specific inference of fraud was contained in two different parts of a complaint. Just as the government could reasonably infer fraud based on separate allegations in a journal article and a House report, the government could also reasonably infer fraud from allegations made in separate parts of a complaint.

Even if this inference were unreasonable, it was sufficient that prior publicly available cases mentioned both a change in the design specifications and fraud surrounding the manufacture of the leads, because these allegations, even each taken alone, reveal the true state of facts: a change in the product design after FDA approval.

Therefore, since information was publicly available about the true state of facts and the false state of facts underlying the alleged fraud in the *qui tam* action, the jurisdictional bar of the False Claims Act requires dismissal of the current case.

2. Disclosure of Fraud

Even if this Court concluded that the false and true states of facts had not been disclosed, it could still find a prior disclosure of the fraud itself sufficient to trigger the jurisdictional bar of the False Claims Act. The relators argue that the prior allegations that Medtronic misrepresented how safe its leads were do not constitute the same fraud on the FDA that they alleged. Further, they argue, while the prior cases alleged only fraud on the FDA, this case alleges Medicare fraud.

However, in *Dingle*, we held that a specific allegation of fraud is not necessary. So long as the disclosed fraud puts the government on notice of the "possibility of fraud" surrounding the product or transaction, the prior disclosure is sufficient. *Dingle*, 388 F.3d at 214. For example, in *Dingle* a House Report identified FDA citations for "deviations" from the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* The report did not specifically identify these deviations; it merely stated their existence. *Id.* The Court found this to be sufficient to constitute notice of fraud under the False Claims Act. *Id.* The notice of deviations from the FDCA "allow[ed] a reader to strongly infer that BioPort was not producing its vaccine in line with the FDA requirements." *Id.*

Here, the prior allegations stated that the leads were not as safe as had been reported to the FDA. The prior allegations also alleged fraudulent manufacture and design deviations. The fraud alleged in the *qui tam* action is based on Medtronic's failure to disclose changes to the product as allegedly required by law, thus rendering the product unapproved by the FDA. While both allegations include claims of fraud on the FDA, the two types of fraud on the FDA are slightly different. However, the allegation of fraud on the FDA in relation to the leads in combination with the allegation of fraudulent manufacture and design deviation was sufficient to put the government on notice of the "possibility of fraud" surrounding the manufacture and design of the leads. The allegations provided enough information for the government to infer that Medtronic was not manufacturing the leads in line with FDA requirements and were therefore sufficient to put the government on notice of the possibility of fraud.

Further, although the allegations in the prior cases referred to a slightly different type of fraud than the fraud alleged in the current case, such allegations were sufficiently general that they could encompass the fraud alleged in the *qui tam* action. The relators in *Dingle* argued that the House testimony and report

did not refer to the same allegations of fraud as alleged in the *qui tam* action. *Id.* at 213. However, the *Dingle* Court recognized that, although the House testimony may have concerned a slightly different type of fraud, the information conveyed was more general and could have referred to several types of fraud, including the fraud at issue in the *qui tam* case. *Id.* Here similarly, the prior allegations of fraud on the FDA were sufficiently general, and like the allegations in *Dingle*, could have encompassed the claim of manufacturing fraud and design deviations surrounding the platinum sputter coating on the leads.

The prior allegations concerning Medtronic's misrepresentations to the FDA are sufficient to bar the relators' Medicare fraud claim, as well. The relators argue that Medtronic's changes to the platinum sputter coating rendered the leads unapproved by the FDA. Medtronic defrauded Medicare when it induced Medicare to pay for unapproved leads, the relators allege, because approval is a precondition for Medicare coverage. As the district court noted, a Medicare coverage rule "provides an inference that the marketing of non-FDA-approved devices would have an impact on Medicare claims." Although the district court concluded otherwise, we conclude that the prior allegations of fraud on the FDA notified the government of the possibility of Medicare fraud associated with these Medtronic products.

B. Based Upon the Disclosed Fraud

The next question before us is whether the claim is based upon the disclosed fraud. This Court has held that a complaint is "based upon" the public disclosure where it is "supported by [the public disclosure] and includes any action based even partly upon public disclosures." *United States ex rel. Jones v. Horizon Healthcare Corp*, 160 F.3d 326, 332 (6th Cir. 1998) (internal quotations omitted); *see also Bledsoe*, 342 F.3d at 646; *McKenzie*, 123 F.3d at 938.

The district court found that jurisdiction was proper because the *qui tam* action was not based upon prior allegations of Medicare fraud. Specifically, the district court found that "[d]efendant has not shown a public record which specifically alleges that a particular patient had a Model 4004/M lead implanted *and* that this procedure and implant were paid for by Medicare." (emphasis in original). However, the Medicare fraud claim necessarily relies on the FDA fraud claim. Without FDA fraud rendering the leads unapproved, there could not have been Medicare fraud, because the submission of Medicare claims for implantation of the leads would have been valid. Therefore, the Medicare fraud claim is based on the public disclosure of fraud on the FDA and jurisdiction under the False Claims Act was inappropriate.

III. CONCLUSION

For the preceding reasons, we **REVERSE** the judgment of the district court and **REMAND** for disposition consistent with this Court's opinion.